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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/658,698 | 09/08/2000 | Samuel C Silverstein | 60467/JPW/GJG | 3655 |

7590 12/13/2001

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EXAMINER

DECLOUX, AMY M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1644 | |

DATE MAILED: 12/13/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------------------------|---|
| Office Action Summary | Application No. 09/658,698 | Applicant(s) Silverstein et al. |
| | Examiner DeCloudx, Amy | Art Unit 1644 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Sep 8, 2000

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-32 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

4b) _____ is/are allowed.

5) Claim(s) _____ is/are rejected.

6) Claim(s) _____ is/are objected to.

7) Claim(s) _____ are subject to restriction and/or election requirement.

8) Claims 1-32 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) Interview Summary (PTO-413) Paper No(s). _____

19) Notice of Informal Patent Application (PTO-152)

20) Other: _____

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DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. This application contains claims directed to the following patentably distinct species of the claimed invention:
 - A) a method comprising a specific particle, such as a type O red blood cell ghost as recited in claims 2 and 18, or a liposome as recited in claims 3 and 19,
 - B) A method comprising a specific ligand, such as one of the ligands recited in claims 4 and 20,
 - C) a method comprising a specific antigen presenting cell as recited in claims 5 and 17,
 - D) a method comprising a specific antigen such as one recited in claims 10 and 22,
 - E) a method comprising a specific stimulatory cytokine such as one recited in claims 12 and 28,
 - F) a method wherein the immunity induced is against a specific antigen or a specific cancerous tumor as recited in claims 13-14 and 29-30,
 - G) a method comprising a specific disease such as one recited in claims 15-16 and 31-32,
 - H) a method wherein delivery of the antigen is administered in a specific manner, such as directly to the subject as recited in claim 1, or ex vivo, as encompassed by claim 17.

For each of the above categories A) through H), applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-32 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

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are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

18. The species are distinct each from the other because the encompassed products differ with respect to their physicochemical properties, and the encompassed diseases differ with respect to their etiology, and the methods of delivery differ with respect to their process steps. Therefore, each of the species is patentably distinct.

19. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
December 11, 2001

David A Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 1644